CLIA ANNUAL LABORATORY REGISTRY 2004

Once a year the Centers for Medicare and Medicaid Services makes available to physicians and to the general public specific information (including information provided to CMS by the Office of the Inspector General) that is useful in evaluating the performance of laboratories. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) and implementing regulations at 42 CFR 493.1850 require that this listing include the following:

- (1) A list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks.
- (2) A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reasons for the adverse actions.
- (3) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the PHS Act, together with circumstances of each case and the penalties imposed.
- (4) A list of laboratories on which alternative sanctions have been imposed, showing--
 - (i) the effective date of the sanctions;
 - (ii) the reason for imposing them;
 - (iii) any corrective action taken by the laboratory;
 - (iv) if the laboratory has achieved compliance, the verified date of compliance.
- (5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.
- (6) All appeals and hearing decisions.
- (7) A list of laboratories against which CMS has brought suit under Section 493.1846 and the reasons for those actions.
- (8) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for exclusion.

Civil settlements reached with clinical laboratories are also noted.

The Laboratory Registry is compiled for the calendar year preceding the date the information is made available and also contains corrections of any erroneous statements of information that appeared in the previous registry. A final section includes other specific information that may be useful in evaluating the performance of laboratories, as specified in 493 CFR 1850(a). It also includes information provided by CLIA exempt states.

2004 CLIA LABORATORY REGISTRY

(As required by Section 353(n) of the Public Health Service Act.)

Activity January 1, 2004 through December 31, 2004

1. LABORATORIES SUBJECT TO CLIA THAT HAVE BEEN CONVICTED, UNDER FEDERAL OR STATE LAWS RELATING TO FRAUD AND ABUSE, FALSE BILLING, OR KICKBACKS.

Stephen Bickel, Director Stat Medical Laboratories 636 West Imboden Drive Decatur, Illinois 62521 CLIA ID# 14D0897623

REASON: Owner of Stat Medical Laboratories Stephen Bickel pled guilty to 2 counts

of mail fraud in October 2003 and was sentenced for false billing Medicare and Medicaid while using his CLIA certificate. He was sentenced to 60 months in prison and order to pay restitution in the amount of \$2,521,577.42. Plea agreement and judgment filed on August

18, 2004.

The following was supplied by the Office of the Inspector General.

Abe Oyamada, Director SGV Laboratory Inc. 221NSan Dimas Ave Suite B San Dimas, California 91773 CLIA ID# 05D0719679

Sol Teitelbaum, Director Medical Diagnostic Laboratories Inc. 10136 Artisia Place Bellflower, California 90706 CLIA ID# 05D0913435

Harry Bauer, Director 1111 W. 6th Street #B1 Los Angeles, California 90017 **CLIA ID# 05D0913912**

Abe Oyamada, Director California Lab Access Inc. 2007 Wilshire Blvd., #303 Los Angeles, California 90057 CLIA ID# 05D0943447

2. LABORATORIES THAT HAVE HAD THEIR CLIA CERTIFICATE SUSPENDED, LIMITED, OR REVOKED, AND THE REASON FOR THE ADVERSE ACTION.

(Medicare cancellation, a principal sanction, has been included in this category.)

Robert Rook, M.D., Director Conway Family Practice 919 Locust Conway, Arkansas 72034 CLIA ID# 04D0713096

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services and revocation of CLIA certificate.

EFFECTIVE DATE: January 5, 2004 (Medicare cancellation)

February 18, 2004 (Revocation)

REASON: Failure to submit an acceptable plan of correction. Condition level

non-compliance.

Patricia G. McGarry, M. D., Director Salem Family Practice Clinic, PA 6640 Congo Road Benton, Arkansas 72015

CLIA ID# 04D0936265

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services. Pending revocation of the CLIA certificate

based on Appeal.

EFFECTIVE DATE: November 8, 2004 (Medicare cancellation)

December 22, 2004 (Revocation)

REASON: Condition level non-compliance; on-site monitoring. Failure to

provide an acceptable Plan of Correction.

Walter Schreiber, M.D., Director 12095 West Washington Blvd. Los Angeles, California 90066-5826

CLIA ID# 05D0545697

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services and revocation of CLIA certificate.

EFFECTIVE DATE: March 20, 2004 (Medicare cancellation)

May 4, 2004 (Revocation)

REASON: Condition level non-compliance.

Shanti Miglani Sahagal, M.D., Director United Medical Reference Laboratory 4125 Verdugo Road Los Angeles, California 90065 CLIA ID# 05D0551448

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services and revocation of CLIA certificate.

EFFECTIVE DATE: October 26, 2004 (Medicare cancellation)

REASON: Condition level non-compliance.

STATUS: Revocation pending appeal.

Jack Wasserman, M.D., Director Scripps Ranch Medical Clinic 9999 Mira Mesa Blvd., #103 San Diego, California 92131

CLIA ID# 05D0571145

SANCTION: Revocation of CLIA certificate.

EFFECTIVE DATE: April 21, 2004

REASON: Improper proficiency testing referral and Condition level non-

compliance.

Dom T. Salamanca, CLB, Director Millennium Clinical Laboratories, Inc. 401 South Flower Street Burbank, California 91502 CLIA ID# 05D0672667

SANCTION: Revocation of CLIA certificate.

EFFECTIVE DATE: September 13, 2004

REASON: Condition level non-compliance causing immediate and serious

threat to the health and safety of patients.

Sukoo J. Whang, M.D., Director Dimensions Medical Laboratories, Inc. 18250 Roscoe Boulevard, Suite 120 Northridge, California 91325 CLIA ID# 05D0724776

SANCTION: Cancellation of approval to receive Medicare payment for

all laboratory services, suspension and revocation of CLIA

certificate.

EFFECTIVE DATE: October 17, 2004 (Medicare cancellation)

October 20, 2004 (CLIA suspension)

REASON: Condition level non-compliance causing immediate and serious

threat to the health and safety of patients.

STATUS: Revocation pending hearing.

Norvelle Harris, M.D., Director Bethesda Pathology Clinical, Inc. 4520 Wilshire Blvd. Suite 104 Los Angeles, California 90010

CLIA ID# 05D0869567

SANCTION: Revocation of CLIA certificate.

EFFECTIVE DATE: February 3, 2004

REASON: CLIA regulation prohibit the owner, operator or director of a

laboratory whose CLIA certificate has been revoked from owning, operating or directing any clinical laboratory for a period of two

years from the date of revocation.

Luis Hernandez, M.D., Director American Diagnostic Labs 9209 South Colima Road, Suite 2300 Whittier, California 90605

CLIA ID# 05D0954736

SANCTION: Revocation of CLIA certificate.

EFFECTIVE DATE: June 9, 2004

REASON: Condition level non-compliance causing immediate and serious

threat to the health and safety of patients.

Issac Melamed, M.D, Director Child First Pediatrics 7336 S Yosemite #200 Englewood, Colorado 80112 CLIA ID# 06D0511723

SANCTION: Limitation of CLIA certificate and limitation of approval receive

Medicare/Medicaid payment for the specialty Hematology.

EFFECTIVE DATE: March 22, 2004

REASON: Condition level non-compliance.

Ashok Khanna, M.D., Director Florida Primary Care Center 2918 N. Pine Hills Road Orlando, Florida 32808 CLIA ID# 10D0275247

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services and revocation of CLIA certificate.

EFFECTIVE DATE: March 29, 2004

REASON: Failure to correct deficiencies. Failure to submit an acceptable

allegation of compliance.

Lee Woodall, M.D., Director 101 Houston Street Barnesville, Georgia 30204 CLIA ID# 11D0257012

SANCTION: Suspension of approval to receive Medicare payment and

limitation of certificate for the analyte, (White Blood Cell).

EFFECTIVE DATE: July 2, 2004

REASON: Condition level non-compliance; failure to successfully perform

proficiency testing.

Gilbert Harris, M.D., Director Athens Associates Family Practice 300 Hawthorne Lane Athens, Georgia 30306 CLIA ID# 11D0261921

SANCTION: Suspension of approval to receive Medicare payment and

limitation of certificate for the analyte (Hemoglobin).

EFFECTIVE DATE: April 17, 2004

REASON: Condition level non-compliance; failure to successfully perform

proficiency testing.

STATUS: Reinstated July 14, 2004

Marilyn Carter, M.D., Director Augusta Assoc of International Medicine and Rheumatolgy 2361 Tobacco Road Augusta, Georgia 30906 CLIA ID# 11D0886932

SANCTION: Suspension of approval to receive Medicare payment and

limitation of certificate (Microbiology).

EFFECTIVE DATE: April 17, 2004

REASON: Condition level non-compliance; failure to successfully perform

proficiency testing.

Lee Rippy M.D., Director Newton Women's Health Center 7129 Floyd Street Covington, Georgia 30014 CLIA ID# 11D0888316

SANCTION: Suspension of approval to receive Medicare payment and

limitation of certificate (Microbiology).

EFFECTIVE DATE: April 17, 2004

REASON: Condition level non-compliance; failure to successfully perform

proficiency testing.

STATUS: Reinstated July 14, 2004

John M. Grzybowski, Director Obstetrical & Gynecological Associates 4945 19th Street Des Moines, Iowa 50314

CLIA ID# 16D0383711

SANCTION: Suspension of approval to receive Medicare payment and

limitation of certificate for the analyte, automated white blood cell

differential.

EFFECTIVE DATE: April 9, 2004

REASON: Condition level non-compliance; failure to successfully perform

proficiency testing.

Lawrence Boas, M.D., Director 54 Scott Adam Road Cockeysville, Maryland 21030 CLIA ID# 21D0214292

SANCTION: Cancellation of approval to receive Medicare payment for all

services; suspension and revocation of the CLIA certificate.

EFFECTIVE DATE: January 26, 2004

REASON: Failure to provide plan of correction for standard-level

deficiencies.

STATUS: Compliance achieved February 11, 2004.

Michael B. Pearlman, M.D., Director 5400 Old Court Road Suite 204 Randallstown, Maryland 21133

CLIA ID# 21D0215728

SANCTION: Cancellation of approval receive Medicare payment for all

laboratory services and suspension of CLIA certificate.

EFFECTIVE DATE: June 28, 2004

REASON: Condition level non-compliance resulting in immediate jeopardy to

the health of patients.

Jesus Socrates, M.D., Director Reference Pathology Services of Maryland 9411 Philadelphia Road Suite J & K Baltimore, Maryland 21237

CLIA ID# 21D0932741

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services and suspension of CLIA certificate.

EFFECTIVE DATE: September 18, 2004

REASON: Condition level non-compliance resulting immediate jeopardy to

the health of patients.

Bruce Britton, Director St Luke Community Hospital 107 6th Avenue SW Ronan, Montana 59864 **CLIA ID# 27D0411099**

SANCTION: Limitation of CLIA certificate and limitation of approval to receive

Medicare/Medicaid payment for the analyte Digoxin.

EFFECTIVE DATE: March 5, 2004

REASON: Condition level non-compliance.

STATUS: Reinstated September 5, 2004.

Trudi Muir, Director Helena Medical Laboratory Inc. 27 Neill Avenue Suite 103 Helena, Montana 59601 CLIA ID# 27D0667170

SANCTION: Limitation of CLIA certificate and limitation of approval to receive

Medicare/Medicaid payment for the analyte Uric Acid.

EFFECTIVE DATE: March 5, 2004

REASON: Condition level non-compliance.

STATUS: Reinstated June 17, 2004

Gerald Yudell, Director 904 Gramatan Avenue Mount Vernon, New York 10552

CLIA ID# 33D0138564

SANCTION: Suspension and revocation of CLIA certificate; cancellation of all

Medicare/Medicaid payment.

EFFECTIVE DATE: June 17, 2004

REASON: Condition level non-compliance resulting in immediate jeopardy to

the health and safety of patient.

STATUS: Certificate revoked; laboratory closed.

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Richard N. Stellar, M.D., Director Long Island Gastroenterology Group 131 West Merrick Road Merrick, New York 11566

CLIA ID# 33D0154446

SANCTION: Suspension of CLIA certificate and payment for all laboratory

services.

EFFECTIVE DATE: July 9, 2004

REASON: Condition level non-compliance; failure to submit an acceptable

plan of correction.

STATUS: Certificate reinstated September 7, 2004.

Michael Dannenberg, M.D., Director Dermatology Associates of Huntington 177 Main Street Huntington, New York 11743

CLIA ID# 33D0157314

SANCTION: Revocation of CLIA certificate and suspension of approval to

receive Medicare payment for all laboratory services.

EFFECTIVE DATE: April 20, 2004

REASON: Failure to submit an acceptable Plan of Correction.

STATUS: Certificate revoked.

John J. O'Donnell, M.D., Director Smithtown Manor Pediatrics 317 Middle Country Road Smithtown, New York 11787-2818

CLIA ID# 33D0159144

SANCTION: Revocation of CLIA certificate and approval to receive Medicare

payment Medicare payment for all laboratory services.

EFFECTIVE DATE: September 21, 2004

REASON: Failure to submit acceptable Plan of Correction.

STATUS: Certificate revoked.

Henry Chinonuma, M.D., Director 7711 Oswego Road Liverpool, New York 13090 CLIA ID# 33D0698093

SANCTION: Suspension of CLIA certificate and suspension of approval to

receive Medicare payment for all laboratory services.

EFFECTIVE DATE: March 27, 2004

REASON: Condition level non-compliance; failure to submit acceptable Plan

of Correction.

Judith Jakus-Capla, M.D., Director 530 First Avenue New York, New York 10016 CLIA ID# 33D0864181

SANCTION: Suspension of CLIA certificate and suspension of approval to

receive Medicare payment for all laboratory services.

EFFECTIVE DATE: October 22, 2004

REASON: Condition level non-compliance; failure to submit an acceptable

Plan of Correction.

STATUS: Certificate revoked.

Charles E. Womack, M.D., Director 5252 N. Meridian, Suite 101 Oklahoma City, Oklahoma 73112

CLIA ID# 37D0471513

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services; cancellation and revocation of CLIA

certificate.

EFFECTIVE DATE: December 26, 2004 (Medicare/cancellation-CLIA/revocation)

REASON: Failure of laboratory to submit compliance fees.

Malcolm E. Bridwell, M.D., Director Village Medical Clinic Inc. 700 North Hill Hobart, Oklahoma 73651 CLIA ID# 37D0472446

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services and suspension of CLIA certificate.

EFFECTIVE DATE: July 27, 2004 (Medicare/cancellation-CLIA/suspension)

REASON: Condition level non-compliance; immediate jeopardy, laboratory

failed to submit an acceptable plan of correction.

STATUS: Compliance achieved September 20, 2004.

Eddie Stewart, Director Stewart Medical Clinic 327 Chickasha Ave Suite #4 Chickasha, Oklahoma 73018-2673

CLIA ID# 37D0889425

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services suspension and revocation of CLIA certificate.

EFFECTIVE DATE: July 14, 2004 (Medicare/cancellation-CLIA/suspension)

REASON: Failure to submit acceptable Plan of Correction.

STATUS: Revocation of CLIA certificate August 31, 2004.

Pravin Gadani, M.D., Director Gadani Assocaiates 30 East Shady Lane Enola, Pennsylvania 17025

CLIA ID# 39D0185771

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services and suspension of CLIA certificate.

EFFECTIVE DATE: July 27, 2004

REASON: Condition level non-compliance resulting in immediate jeopardy to

the health and safety of patients.

Ada E. Quinones, Director Laboratorio Clinico Campo Rico 929 Country Club Avenue San Juan, Puerto Rico 00924 CLIA ID# 40D0693615

SANCTION: Revocation of CLIA certificate and suspension of approval to

receive Medicare payment in Immunohematology. Civil money

penalty of \$10,000.

EFFECTIVE DATE: December 29, 2004

REASON: Improper proficiency testing activities.

STATUS: Hearing requested.

Carmen I. Ocasio, Director Education Medical Group P.O. Box 98 Caguas, Puerto Rico 00659 CLIA ID# 40D0961191

SANCTION: Revocation of CLIA certificate and cancellation of approval to

receive Medicare payment for all laboratory services.

EFFECTIVE DATE: September 27, 2004

REASON: No Plan of Correction submitted.

STATUS: Certificate revoked.

Samuel Gonzalez, M.D., Director Southwest Oncology Clinic Edificio Parra, Suite 801 Ponce, Puerto Rico 00717 CLIA ID# 40D1002294

SANCTION: Revocation of CLIA certificate and cancellation of approval to

receive Medicare payment for all laboratory services.

EFFECTIVE DATE: September 27, 2004

REASON: No Plan of Correction submitted.

STATUS: Certificate revoked.

Maria Del Carmen Aguilar, M.D., Director Clinic Santa Teresa 2136 Yale, Suite A Houston, Texas 77008 CLIA ID# 45D0959691

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services, cancellation and revocation of CLIA

certificate.

EFFECTIVE DATE: May 21, 2004 (Medicare/cancellation)

July 10, 2004 (CLIA revocation)

REASON: Failure to submit compliance fees.

Stephen D. Wood, M.D., Director Foothill Family Clinic 2295 Foothill Drive Salt Lake City, Utah 84109-3957

CLIA ID# 46D0524018

SANCTION: Cancellation of approval to receive Medicare payment for all

services and revocation of CLIA certificate.

EFFECTIVE DATE: March 15, 2004 (Medicare cancellation)

REASON: Improper proficiency testing referral.

STATUS: Revocation pending hearing.

Stephen D. Wood, M.D., Director Foothill Family Clinic - South 6360 S 3000 E Suite 100 Salt Lake City, Utah 84121

CLIA ID# 46D0935188

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services, suspension and revocation of CLIA certificate.

EFFECTIVE DATE: March 15, 2004 (Medicare Cancellation)

REASON: Improper proficiency testing referral.

STATUS: Revocation pending appeal.

G.Q. Khokar, M.D.., Director 1322 Stadium Drive Bluefield, West Virginia 24701 CLIA ID# 51D0881983

SANCTION: Cancellation of approval to receive Medicare payment for all

laboratory services and suspension of CLIA certificate.

EFFECTIVE DATE: April 3, 2004

REASON: Condition level non-compliance resulting in immediate jeopardy to

the health and safety of patients.

STATUS: Compliance confirmed May 27, 2004.

3. A LIST OF PERSONS CONVICTED OF VIOLATING CLIA REQUIREMENTS AS SPECIFIED IN SECTION 353(1) OF THE PUBLIC HEALTH SERVICES ACT, WITH THE CIRCUMSTANCES OF EACH CASE AND THE PENALTIES IMPOSED:

4. A LIST OF LABORATORIES ON WHICH ALTERNATIVE SANCTIONS HAVE BEEN IMPOSED, SHOWING—

- (i) The effective date of the sanctions;
- (ii) The reason for imposing them;
- (iii) Any corrective action taken by the laboratory; and
- (iv) If laboratory has achieved compliance, the verified date of the compliance.

Sybil Hart, M.D., Director Millard-Henry Clinic of Russellville 111 East Main Atkins, Arkansas 72823 CLIA ID# 04D0469021

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: August 10, 2004

REASON: Condition level non-compliance - immediate jeopardy.

STATUS: Compliance achieved September 21, 2004.

Benny Green, M.D., Director 14309 Cantrell Road Suite 7 Little Rock, Arkansas 72223

CLIA ID# 04D0716907

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: August 10, 2004

REASON: Condition level non-compliance – immediate jeopardy.

STATUS: Compliance achieved September 29, 2004.

Patricia G. McGarry, M.D., Director Salem Family Practice Clinic 6640 Congo Road Benton, Arkansas 72015

CLIA ID# 04D0936265

SANCTION: Directed Plan of Correction, State On-Site Monitoring.

EFFECTIVE DATE: November 8, 2004

REASON: Condition level non-compliance.

STATUS: CLIA certificate revoked December 22, 2004.

Internal Medicine & Associates David Furr O.D., Director 2010 Chestnut Suite H Van Buren, Arkansas 72956 CLIA ID# 04D1021327

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: October 18, 2004

REASON: Condition level non-compliance - immediate jeopardy.

STATUS: Compliance achieved December 12, 2004.

Walter Schreiber, M.D., Director 12095 West Washington Blvd Los Angeles, California 90066-5826

CLIA ID# 05D0545697

SANCTION: Civil Money Penalty of \$3,000 per day and Directed Portion of

Plan of Correction.

EFFECTIVE DATE: March 20- May 4, 2004 (Civil Money Penalty)

March 20, (Directed Plan of Correction)

REASON: Condition level non-compliance.

STATUS: CLIA Certificate revoked May 4, 2004.

Shanti Miglani Sahgal, M.D., Director United Medical Reference Laboratory 4125 Verdugo Road Los Angeles, California 90065

CLIA ID# 05D0551448

SANCTION: Civil Money Penalty of \$3,000 and Portion of a Plan of Correction.

EFFECTIVE DATE: October 26, 2004

REASON: Condition level non-compliance.

STATUS: Revocation pending appeal.

Sukoo J. Whang, M.D., Director Dimensions Medical Laboratories, Inc. 18250 Roscoe Blvd. Suite 120 Northridge, California 91325

CLIA ID# 05D0724776

SANCTION: Civil Money Penalty of \$3,000 per day and Directed Portion of

Correction.

EFFECTIVE DATE: October 17, 2004

REASON: Condition level non-compliance causing immediate and serious

threat to the health and safety of patients.

STATUS: Revocation pending appeal.

Hal Ridgeway M.D., Director Forest Hill Dermatology Associates 3400 Forest Hill Blvd. West Palm beach, Florida 33406

CLIA ID# 10D0687272

SANCTION: Civil Money Penalty of \$6,500 per day and Directed Plan of

Correction.

EFFECTIVE DATE: September 23, 2004

REASON: Condition level non-compliance; testing outside of CLIA

certificate.

Michael B. Pearlman, M.D., Director 5400 Old Court Road Suite 204 Randallstown, Maryland 21133

CLIA ID# 21D0215728

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: May 14, 2004

REASON: Unsuccessful participation in proficiency testing.

STATUS: Limitation of CLIA certificate and cancellation of approval to

receive Medicare payment for the red blood cell (RBC) analyte.

John Braun, M.D., Director Maryland General Hospital Laboratory 827 Linden Avenue Baltimore, Maryland 21201

CLIA ID# 21D0665870

SANCTION: Plan of Correction and State Onsite Monitoring.

EFFECTIVE DATE: June 16, 2004

REASON: Condition level non-compliance.

STATUS: Compliance achieved August 4, 2004.

Robert S. Fredericks, M.D., Director Endocrine Associates 540 W. Plumb Lane, Suite 2A Reno, Nevada 89509 CLIA ID# 29D0539692

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: November 4, 2004

REASON: Condition level non-compliance; unsuccessful participation in

proficiency testing.

STATUS: Approval to receive Medicare payment for the subspecialty of

routine chemistry cancelled on November 4, 2004 for a period

not less than six months.

Razia S. Rehman, M.D., Director Cornell Clinicals Inc. 171 Elmora Avenue Elizabeth, New Jersey 07202

CLIA ID# 31D0947675

SANCTION: Civil Money Penalty of \$1,983.

EFFECTIVE DATE: July 9, 2004

REASON: Condition level non-compliance - immediate jeopardy.

STATUS: Laboratory ceased prothrombin time and INR testing.

Sushila Varadarajan, M.D., Director Med Tech Clinical Laboratory Inc. 438 Ganttown Road, Suite B-8 Sewell, New Jersey 08080

CLIA ID# 31D1002581

SANCTION: Civil Money Penalty of \$3,500.

EFFECTIVE DATE: July 27, 2004

REASON: Condition level non-compliance – immediate jeopardy.

STATUS: Immediate jeopardy removed. Hearing requested. Settlement

agreement on December 22, 2004. Laboratory ceased prothrombin

time and INR testing. CMP paid.

Patric Y. Nassaux, M.D., Director Crownpoint Healthcare Facility Highway 371 & Navajo 9 P.O. Box 358 Crownpoint, New Mexico 87313

CLIA ID# 32D0536088

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: September 11, 2004

REASON: Condition level non-compliance – Immediate Jeopardy.

Joseph Gardith, M.D., Director HemOnCare, PC 2558 E 18th Street, Corner Avenue Z Brooklyn, New York 11234

CLIA ID# 33D0147881

SANCTION: Civil Money Penalty of \$487.50.

EFFECTIVE DATE: December 23, 2004

REASON: Condition-level noncompliance after denial of accreditation by

COLA.

STATUS: Civil Money Penalty Paid.

Ezra Bendit, M.D., Director 1181 Old Country Road Plainview, New York 11803

CLIA ID# 33D0680788

SANCTION: Civil Money Penalty of \$1,300.

EFFECTIVE DATE: December 23, 2004

REASON: Condition-level noncompliance after denial of accreditation by

COLA.

STATUS: Civil Money Penalty Paid.

Jill Waton, M.D., Director Purcell Municipal Hospital 1500 N. Green Avenue Purcell, Oklahoma 73080-1642

CLIA ID# 37D0470030

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: August 10, 2004

REASON: Condition level non-compliance – Immediate Jeopardy.

STATUS: Compliance achieved October 11, 2004.

Malcolm E. Bridwell, M.D., Director Village Medical Clinic Inc. 700 North Hill Hobart, Oklahoma 73651

CLIA ID# 37D0472446

SANCTION: Directed Plan of Correction; Technical Assistance and Training.

EFFECTIVE DATE: July 27, 2004

REASON: Condition level non-compliance – Immediate Jeopardy;

demonstration of unsuccessful participation proficiency testing.

STATUS: Compliance achieved September 20, 2004.

Axel Arroyo, M.D., Director Laboratorio Clinico Hospital Damas, Inc. 2213 Ponce By Pass Ponce, Puerto Rico 00717

CLIA ID# 40D0658169

SANCTION: Civil Money Penalty of \$10,465.

EFFECTIVE DATE: October 28, 2004

REASON: Condition level non-compliance – Immediate Jeopardy.

STATUS: Immediate Jeopardy removed. Civil Money Penalty paid.

Nieva R. Ladrilllono, MS, MT., Director Planned Parenthood of Southeast Virginia 425 West 20th Street Suite 6 Norfolk, Virginia 23517 **CLIA ID# 49D0230416**

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: January 17, 2004

REASON: Unsuccessful participation in proficiency testing.

STATUS: Compliance achieved March 18, 2004.

Kyle F. Fort, M.D., Director Greenbrier Valley Urology Associates, Inc. 119 Maplewood Avenue at Fairlea Ronceverte, West Virginia 24970

CLIA ID# 51D0233762

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: March 11, 2004

REASON: Unsuccessful participation in proficiency testing.

STATUS: Compliance achieved May 11, 2004.

The following was supplied by the State of New York under their CLIA Exempt Status:

Alfred Seipp, Director Vitamin Diagnostics Inc. RT #35 & Industrial Drive Cliffwood Beach, New Jersey 07735-6113

CLIA ID# 31D0710366

SANCTION: Denial of Seipp's application for a Director Certificate of

Qualification.

EFFECTIVE DATE: July 6, 2004

REASON: Unwillingness or inability to fulfill the duties and responsibilities

of director evidenced by deficiencies at two laboratories operating

under his direction.

Milton Eke, Director TL Clinical Laboratory 238 Rockaway Ave

Valley Stream, New York 11582

CLIA ID# 33D0155229

SANCTION: Denial of Eke's application for a laboratory director Certificate of

Qualification.

EFFECTIVE DATE: April 6, 2004

REASON: False representation of material on application.

Anne Platt, M.D., Director Enzo Clinical Labs, Inc. 60 Executive Blvd

Farmingdale, New York 11735-4716

CLIA ID# 33D0159701

SANCTION: Civil penalty of \$2000, and imposed plan of correction to ensure

laboratory's procedure for participation in proficiency testing (PT)

effectively prevent sharing of results between two sites.

EFFECTIVE DATE: October 7, 2004

REASON: PT misrepresentation. The parent laboratory performed antigen

detection analysis on streptococcus PT samples intended for processing by a separate facility under the same ownership, and in reporting results, misrepresented the location of actual testing and

analyst who performed the testing.

Claude Neptune, Director Pathlab 241 37th Street Brooklyn, New York 11232 CLIA ID# 33D0654096

SANCTION: Letter of reprimand to laboratory director that imposes a

requirement for Department approval prior to acceptance of a

director position with a regulated facility.

EFFECTIVE DATE: February 25, 2004

REASON: PT misrepresentation. In reporting results for a toxicology PT

challenge, the laboratory misrepresented the analyst who

performed the test.

Charles Pavia, Director
Infectious Diseases Immundiagnostic Laboratory
Macy Pavillion W Medical Center
Valhalla, New York 10595
CLIA ID# 33D0927933

SANCTION: Denial of Pavia's application for laboratory director Certificate of

Qualification.

EFFECTIVE DATE: May 27, 2004

REASON: Unwillingness or inability to fulfill effectively the duties and

responsibilities of a director as evidenced by deficiencies at a

laboratory operating under his direction.

Gladys Ngozi Ibezim, Director GLADZIM Medical & Scientific Lab, Inc. 215 Rockaway Avenue Brooklyn, New York 11233 CLIA ID# 33D0995496

SANCTION: Denial of application for a laboratory certificate.

EFFECTIVE DATE: September 15, 2004

REASON: Unwillingness or unable to bring the laboratory into compliance

with certificate requirements.

5. LABORATORIES WHOSE ACCREDITATION HAS BEEN WITHDRAWN OR REVOKED AND THE REASON FOR THE WITHDRAWAL OR REVOCATION.

Jamie Kapner, M.D., Director 10250 N 92nd Street Suite 100 Scottsdale, Arizona 85258

CLIA ID# 03D0530323 (COLA #15124)

SANCTION: Denial of Accreditation.

EFFECTIVE DATE: December 2, 2004

REASON: Failure to adhere to COLA imposed required improvements;

failure to comply with reasonable requests of COLA.

Donald L. Tscirhart, M.D., Director St. Vincent Medical Center 2131 West Third Street Los Angeles, California 90057 CLIA ID# 05D0545353 (CAP)

SANCTION: Denial of Accreditation.

EFFECTIVE DATE: December 28, 2004

REASON: Condition of a non-routine inspection to be conducted in March

2005 due to the recurrent deficiencies identified at the September

27, 2004 routine inspection.

STATUS: Laboratory implemented corrective action for all deficiencies,

laboratory is currently accredited.

James Gibbs, M.D., Director Community Hospital of Huntington Park Clinical Laboratory 2623 East Slauson Avenue Huntington Park, California 90255 CLIA ID# 05D0548135 (CAP)

SANCTION: Denial of Accreditation.

EFFECTIVE DATE: December 28, 2004

REASON: Condition of a non-routine inspection to be conducted in March

2005 due to the recurrent deficiencies identified at the October 20,

2004 routine inspection.

STATUS: Laboratory implemented corrective action for all deficiencies,

laboratory is currently accredited.

Benito Villanueva, M.D., Director IGO Medical Group Laboratory 9339 Genesee Avenue Suite 220 San Diego, California 92121-2196 CLIA ID# 05D0683043 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: December 13, 2004

REASON: Condition of a non-routine inspection to be conducted in March

2005 due to the lack of Medical Director involvement identified at

the September 24, 2004 non-routine inspection.

STATUS: Laboratory implemented corrective action for all deficiencies,

laboratory is currently accredited.

James J. Norton, M.D., Director Cyto Temps, Inc. 9520 Padgett Street, Suite 105 San Diego, California 92126-4442 CLIA ID# 05D0939434 (CAP)

SANCTION: Denial of Accreditation.

EFFECTIVE DATE: October 20, 2004

REASON: Non-compliance with standards for Accreditation as evidenced by

the number and severity of deficiencies identified during a routine inspection on June 11, 2004 and the inadequate actions to those

deficiencies.

Oscar A. Soto, M.D., Director Medical Arts Complex 4701 North Federal Highway Fort Lauderdale, Florida 33308

CLIA ID# 10D0284154 (COLA #4562)

SANCTION: Denial of Accreditation.

EFFECTIVE DATE: June 2, 2004

REASON: Continuing to test an analyte, specialty or subspecialty after being

directed by COLA to cease testing. Failure to meet proficiency testing requirements; Failure to adhere to COLA imposed required

improvements; failure to comply with reasonable request of

COLA.

Jorge H.Cacers, Director World Diagnostic Medical Laboratory 4111 SW 47th Ave# 331 Davie, Florida 33314

CLIA ID# 10D1010037 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: November 23, 2004

REASON: Non-compliance with CAP Standards for Accreditation as

evidenced by the number and severity of deficiencies identified

during a non-routine inspection on November 19, 2004.

Lev B. Klempner, Director Lakewood Ranch Medical Center Laboratory 8330 Lakewood Ranch Blvd. Lakewood Ranch, Florida 34202 CLIA ID# 10D1026767 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: November 16, 2004

REASON: Non-compliance with CAP Standard for Accreditation as

evidenced by the number and severity of deficiencies identified

during a non-routine inspection on November 8-10 2004.

Kolavennu Krishnaiah, PhD., Director Glass Clinical Laboratory 2711 W. 183rd Street Homewood, Illinois 60430

CLIA ID# 14D0646517 (COLA# 15888)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: December 2, 2004

REASON: Failure to adhere to COLA imposed required improvements;

failure to comply with reasonable request of COLA

Louis D. Dubllier, M.D., Director Central Laboratory 3301 Leestown Road Lexington, Kentucky 40511 CLIA ID# 18D0682397 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: November 16, 2004

REASON: Non- compliance with CAP Standards for Accreditation as

evidence by the number severity of deficiencies identified during a

non-routine inspection on October 6 2004.

Judith Hackett M.D., Director 1901 Leonidas Street New Orleans, Louisiana 70118 CLIA ID# 19D0459294 (COLA #11592)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: December 2, 2004

REASON: Failure to adhere to COLA imposed required improvements;

failure to comply with reasonable request of COLA.

Alan Spires, M.D., Director Mer Rouge Medical Center 301 Davenport Ave. P.O. Box 429 Mer Rouge, Louisiana 71261 CLIA ID# 19D0464385 (COLA #11323)

> SANCTION: Denial of Accreditation

EFFECTIVE DATE: February 23, 2004

REASON: Continue to test an analyte specialty or subspecialty after being

> directed by COLA to cease testing because of failure to meet proficiency testing requirements. Failure to adhere to COLA

imposed required improvements; failure to comply with reasonable

require of COLA

Floyd Robert M.D., Director Baton Rouge General Medical Center Respiratory Care Laboratory 3600 Florida Boulevard Baton Rouge, Louisiana 70806 CLIA ID# 19D0649209 (CAP)

> SANCTION: Denial of Accreditation

EFFECTIVE DATE: October 20, 2004

REASON: Probation of the laboratory due to significant number and severity

of deficiencies identified during compliance inspection on

September 30 and October 1, 2004. Deficiencies corrected during

routine inspection January 12, 2005.

STATUS: Compliance achieved January 25, 2004.

John Braun M.D., Director Maryland General Hospital 827 Linden Avenue Baltimore, Maryland 21201 CLIA ID# 21D0665870 (CAP)

Denial of Accreditation SANCTION:

EFFECTIVE DATE: May 4, 2004

REASON: Suspension of the disciplines of Chemistry and Point of Care

Testing for non-compliance with CAP Standards for Accreditation

in Chemistry and Point of Care Testing as indicated by the seriousness and recurrence of deficiencies identified during a focused non-routine inspection on April 26, 2004. Laboratory initiated action to correct deficiencies On August 31, 2004 suspension was lifted and Chemistry and Point of Care Testing

were placed on probation.

STATUS: Laboratory is currently accredited with Chemistry and Point of

Care on probation.

Jesus Francisco Urbi Socrates M.D., Director Reference Pathology Services of Maryland Suite J & K 9411 Philadelphia Road Baltimore, Maryland 21237 CLIA ID# 21D0932741 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: May 28, 2004

REASON: Non-compliance with CAP Standards for Accreditation as

identified during a non-routine complaint inspection conducted on May 19, 2004. Issues related to laboratory directorship, reuse of cytology filters in violation of manufacturer's instructions and

violation of cytotechnologist workload limits.

Kenneth D. Asher, Director Jackson Family Clinic 545 Broadridge Drive Jackson, Missouri 63755-3001

CLIA ID# 26D0442079 (COLA #692)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: February 23, 2004

REASON: Failure to adhere to COLA imposed required improvements;

failure to comply with reasonable requests of COLA.

Eric Sheffer M.D., Director A LABCORP Company 100 MacGregor St. Manchester, New Hampshire 03102

CLIA ID# 30D0993032 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: November 19, 2004

REASON: Condition of providing documentation due to the laboratory's

inability to correct space deficiencies, identified during the routine

inspection, prior to re-accreditation.

STATUS: Laboratory implemented corrective action for all deficiencies. The

laboratory is currently accredited.

Edward Andujar M.D., Director Alternacare 516 East Wood Street Vineland, New Jersey 08360

CLIA ID# 31D0858401 (COLA 7537)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: August 26, 2004

REASON: Failure to adhere to COLA imposed required improvements.

Failure to comply with reasonable requests to COLA.

Mark S. Lifshitz M.D., Director New York University Medical Center Clinical Laboratories 560 First Avenue New York, New York 10016 CLIA ID# 33D0653358 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: October 14, 2004

REASON: Condition of providing additional documentation due to the

laboratory's inability to completely correct deficiencies, identified

during the routine inspection, prior to re-accreditation.

STATUS: The laboratory has initiated correction of all deficiencies and is

currently accredited.

Dragoslava B. Zamurovic M.D., Director Sound Shore Medical Center Main Laboratory 16 Guion Place New Rochelle, New York 10802 CLIA ID# 33D0653713 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: October 14, 2004

REASON: Condition of providing documentation of implementation of

corrective actions taken in response to deficiencies identified

during the routine inspection.

STATUS: The laboratory initiated corrective actions and provided

documentation. The laboratory is currently accredited.

Mark Ballow M.D., Director Kaleida Health Children's Hospital Pathology Laboratory 219 Bryant Street Buffalo, New York 14222 CLIA ID# 33D0654779 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: July 27, 2004

REASON: Condition of non-routine to be conducted in March 2005 due to the

number and nature of deficiencies identified at the February 25,

2004 routine inspection.

STATUS: The laboratory implemented corrective actions for all deficiencies

and is currently accredited.

Bruce M. Wenig M.D., Director St.Lukes Roosevelt hospital Center 1000 Tenth Street New York, New York 10019 CLIA ID# 33D0685435 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: October 15, 2004

REASON: Condition of providing monthly reports of surgical pathology

turnaround time to CAP based on deficiencies identified during

routine inspection in January.

STATUS: Laboratory initiated corrected action and provided monthly reports

and is currently accredited.

John F. Russo, Director

Good Samaritan Regional Medical Center

Main Laboratory

700 E. Norwegian Street

Pottsville, Pennsylvania 17901-2798

CLIA ID# 39D0012193 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: August 18, 2004

REASON: Conditions of a non-routine inspection in April 2004 due to the

number of deficiencies and the quality of response to those

deficiencies identified at the routine inspection.

STATUS: The laboratory implemented corrective action and is currently

accredited.

Jeffrey Null, M.D., Director Hazelton Saint Joseph Medical Center Laboratory North Church & Ninth Streets Hazelton, Pennsylvania 18201

CLIA ID# 39D0012372 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: November 3, 2004

REASON: Suspension of the discipline of Transfusion Medicine for non-

compliance with CAP Standards for Accreditation in Transfusion Medicine. Laboratory failed to provide satisfactory response to deficiencies identified during complaint inspection conducted September 22, 2004. The remainder of the laboratory was placed

on probation.

STATUS: The laboratory initiated corrective action and required to submit

monthly progress reports to CAP. Laboratory is currently

accredited, with Transfusion Medicine suspended.

Michael W. Lapinski, M.D., Director Warren General Hospital 2 Crescent Park Warren, Pennsylvania 16365 CLIA ID# 39D0183697 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: September 7, 2004

REASON: Condition of a non-routine inspection conducted due the number

and nature of deficiencies identified at the May 2004 routine

inspection.

STATUS: The laboratory implemented corrective action and is currently

accredited.

Jeffrey A. Null M.D., Director Hazelton General Hospital Laboratory 700 E Broad Street Hazelton, Pennsylvania CLIA ID# 39D0191367 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: September 24, 2004

REASON: Noncompliance with CAP Standards for Accreditation as

evidenced by the number and severity of deficiencies, as well as the number of recurrent deficiencies, identified during a nonroutine complaint inspection conducted on May 4, 2004. Raymond A. Rogowski M.D., Director SMA Medical Laboratories, Inc. 940 Penn Blvd., Unit E Feasterville Trevose, Pennsylvania 19053 **CLIA ID# 39D0987158 (CAP)**

SANCTION:

EFFECTIVE DATE: August 25, 2004

REASON: Condition of a non-routine inspection to be conducted due to

limited number of records available at the initial inspection conducted on June 25, 2004. The laboratory had began testing at

the time of the initial inspection.

STATUS: The laboratory provided appropriate responses to all deficiencies

and is currently accredited.

Denial of Accreditation

G.M.Gollauudi, M.D., Director Diabetes Center of the Southwest 10 Desta Drive Suite 190 Midland, Texas 79705-4514

CLIA ID# 45D0508756 (COLA #2452)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: June 2, 2004

REASON: Failure to adhere to COLA imposed required improvements;

failure to comply with reasonable request of COLA.

Richard Hare, M.D., Director Plaza Medical Center of Fort Worth Main Laboratory 900 8th Avenue Fort Worth, Texas 76104 **CLIA ID# 45D0052440 (CAP)**

SANCTION: Denial of Accreditation

EFFECTIVE DATE: May 6, 2004

REASON: Condition of notifying the CAP of any delays in planned

renovation of laboratory due to the laboratory's inability to correct

space deficiencies identified during March 4, 2004 routine

inspection, prior to re-accreditation.

STATUS: The laboratory has provided a plan for renovation and is currently

accredited.

Bryan Bartlett, M.D., Director Baylor All Saints Medical Center Main Laboratory 1400 8th Avenue Fort Worth, Texas 76104-4110 CLIA ID# 45D0668698 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: September 10, 2004

REASON: Condition of a non-routine inspection to be performed due to the

laboratory inability to correct space deficiencies, identified during

the June 2004routine inspection, prior to re-accreditation.

STATUS: The laboratory provided a satisfactory plan for addressing the

deficiencies and is currently accredited.

Murray D. Solomon, M.D., Director Ennis Regional Medical Center Laboratory 801 West Lampasas Ennis, Texas 75119

CLIA ID# 45D0680542 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: October 20, 2004

REASON: Probation of the laboratory due to inadequate correction of

deficiencies confirmed during non-routine inspection June 2004.

STATUS: Laboratory corrected deficiencies January 2005 and is currently

accredited.

Fernando Lombana, M.D., Director Tejas Medical & Dental Center 2323 Wirt Road Suite F Houston, Texas 77055-1231

CLIA ID# 45D0876360 (COLA #7867)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: December 6, 2004

REASON: Failure to adhere to COLA imposed required improvements;

failure to comply with reasonable requests of COLA.

Warren Bannister, Director Harrisonburg Cytopathology 337 Cub Lane Mac Gaheyville, Virginia 22840 CLIA ID# 49D0661086 (CAP)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: October 20, 2004

REASON: Probation of the laboratory due to significant number and severity

of deficiencies identified during non-routine inspection October

2004.

STATUS: Laboratory initiated correction of deficiencies, had a non-routine

inspection on January 2005 and is currently accredited with

probation.

6. ALL APPEALS AND HEARING DECISIONS.

For detailed information regarding the following listing see CLIA Hearing Decision Index at http://www.cms.gov/clia/hearinggroup.asp

<u>Immuno Biogene Inc.</u> Decision for CMS

Charles Black. M.D., Director v. CMS

23101 Sherman Place Suite 404 10/6/2004

West Hills, California 91307

CLIA ID# 05D0542702

<u>Millennium Clinical Laboratories</u>

Decision for CMS

Dom T. Salamanca, Director v. CMS 9/13/2004

401 South Flower Street

Burbank, California 91502 **CLIA ID# 05D0672667**

American Diagnostic Labs Decision for CMS

<u>Luis Hernandez, M.D., Director v CMS</u> 6/9/2004

9209 South Colima Road, Suite 2300

Whittier, California 90605 **CLIA ID# 05D0954736**

White Lake Family Medicine Decision for CMS

David Leszkowitz Director v. CMS 11/9/2004

9178 Highland Road Suite 1

White Lake, Michigan 488386-2032

CLIA ID# 23D0697765

<u>Vijay Sakhuja, M.D., Director v. CMS</u>

Decision for CMS

146 14 Hillside Avenue 4/19/2004 Jamaica, New York 11435

CLIA ID #33D0907221

7. A LIST OF LABORATORIES AGAINST WHICH CMS HAS BROUGHT SUIT UNDER SECTION 493.1846 AND THE REASON FOR THOSE ACTIONS.

8. A LIST OF LABORATORIES THAT HAVE BEEN EXCLUDED FROM PARTICIPATION IN MEDICARE OR MEDICAID AND THE REASON FOR EXCLUSION.

9.	CORRECTION OF ANY ERRONEOUS STATEMENTS OF INFORMATION
	THAT APPEARED IN THE 2003 REGISTRY.

10. OTHER ACTIONS. THIS SECTIONS INCLUDES OTHER SPECIFIC INFORMATION THAT MAY BE USEFUL IN EVALUATING THE PERFORMANCE OF LABORATORIES, AS SPECIFIED IN 493 CFR 1859(A). IT ALSO INCLUDES INFORMATION PROVIDED BY CLIA EXEMPT STATES.

SETTLEMENTS

The following was supplied by the Office of the Inspector General:

Quest Diagnostics, Inc.

1 Malcolm Avenue
Teterboro, New Jersey 07608
Settlement date: 03/03/2004
ISSUE: False Claims

Medipath Expresss, Inc. 666 Plainsboro Road Plainsboro, New Jersey 08302 **Settlement date:** 09/21/2004

ISSUE: False Claims

MR&S, Inc., d/b/a Atherotech, Inc. 201 London Parkway
Birmingham, Alabama 07816
Settlement date: 04/01/2004
ISSUE: False Claims

Health Line Clinical Laboratories Inc. 3601 West Alameda
Burbank, California 91505
Settlement date: 05/12/2004

ISSUE: False Claims

Balco Laboratories 1520 Gilbreth Road Burlingame, California 94010 **Settlement date:** 09/03/2004

ISSUE: Unjust enrichment and payment by mistake of fact.